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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: Amicus Therapeutics, Inc. Securities Litigation	Case No. 3:15-cv-07350-FLW-DEA *Consolidated with 3:15-cv-07380 and 3:15-cv-07448 (per Dkt. No. 40)* **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT** ***Jury Trial Demanded***

Lead Plaintiff Dr. Barry Brenner ("Plaintiff"), by and through his attorneys, alleges upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based upon the investigation conducted by his attorneys (which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission ("SEC"), news reports, press releases issued by Defendants, and other publicly available documents and information), as follows:

Nature and Summary of the Action

1. This is a case about a small biopharmaceutical company called Amicus Therapeutics, Inc. ("Amicus" or the "Company") and its Chief Executive Officer, John F. Crowley ("Crowley"), who misled investors about the outcome of a critical meeting with the Food and Drug Administration ("FDA") held on or around September 15, 2015. After this meeting with the FDA concluded, Amicus issued a press release in which it stated that "[b]ased on FDA feedback at the Pre-NDA meeting . . . Amicus remains on track to submit an NDA in the fourth quarter of 2015 under Accelerated Approval." Crowley was quoted in the press release as saying that the meeting was "collaborative," and represented a "significant milestone," and was a "great example of FDA and industry working together to advance innovative therapies for people living with debilitating genetic disorders."

2. Crowley informed investors that the meeting "further reinforce[d] our confidence in [Amicus' new drug application] package and post-marketing confirmatory study we are preparing for submission by the end of this year."

3. But no such thing happened at the FDA meeting. Instead, the FDA informed Amicus that it would need to conduct additional studies and/or prepare additional data before it submitted its application for approval of its new drug. In other words, Amicus misled investors as it would *not* be able to submit its NDA by the end of 2015. Crowley misled investors in expressing his "reinforced confidence" in Amicus' ability to submit its NDA by the end of 2015, as the FDA's required additional studies and/or data from Amicus made a year-end 2015 NDA filing an impossibility.

4. When the Company admitted, 17 days later that the meeting had not gone well, that the FDA wanted additional data analysis and studies, and that an application for approval of the company's main drug, migalastat (also called Galafold), would not be submitted in 2015 as originally planned, Amicus' stock price plunged from $13.75 to $5.98, a drop of over 56%, costing investors nearly one billion dollars.

5. On a conference call with stock market analysts after the corrective disclosure was made, Crowley admitted that the FDA was requiring Amicus to provide additional information before its NDA could be submitted. That same day,

October 2, 2015, a J.P. Morgan analyst said that the newly disclosed delay "come[s] as a surprise given prior rhetoric," from the Company, and that "given prior updates, there now appears to be a management credibility issue."

6. Between September 15, 2016 and October 2, 2016, Amicus was scheduled to purchase another small privately held biotechnology company, Scioderm, Inc. ("Scioderm"). That transaction closed shortly after the Company's misinformation about the September 15 FDA meeting and just two days before Amicus revealed the truth about the meeting to the stock market.

7. Not only was Crowley Amicus' President and Chief Executive Officer, he also served on the Board of Scioderm. Tellingly, when Amicus originally announced the acquisition of Scioderm, it promised to do so using a certain ratio of cash and stock. But when the deal closed (after the false statements about the FDA meeting were made, but before the truth was revealed to the market), that mix had changed. Amicus paid for Scioderm with *more* cash and *fewer* shares, revealing that Crowley knew exactly what was coming, and wanted to provide Scioderm shareholders (like himself) with more cash and fewer Amicus shares that were soon to be worth much less.

8. In addition, other Amicus insiders sold over $1.2 million in shares of Amicus in the two weeks between the meeting with the FDA on September 15, 2016 and Amicus' about-face on October 2, 2016. Had those insiders waited until

after the truth was disclosed on October 2, 2016, they would have made $720,000 less in their stock sales.

9. Amicus develops drugs to treat rare diseases, such as Fabry and Pompe. These are debilitating and devastating conditions, and there is little doubt that Amicus is doing important work. Its intentions to serve those suffering are not in question. But when Amicus became a publicly traded company and sought investment from the general public, its executives undertook a promise not to defraud investors. Amicus, Crowley, and Amicus' Chief Medical Officer Jay A. Barth ("Barth") have failed to live up to that promise; they should be held accountable for committing securities fraud.

Jurisdiction & Venue

10. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

12. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by

the District Court permissible under traditional notions of fair play and substantial justice.

13. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), as Amicus has its principal executive offices located in this District and conducts substantial business therein.

14. In connection with the acts, omissions, conduct, and other wrongs described in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, and the facilities of national securities exchanges.

Parties

15. Plaintiff is an individual residing in Wellesley, Massachusetts. Plaintiff acquired and held shares of Amicus at artificially inflated prices during the Class Period and has been damaged by the revelation of Amicus' material misrepresentations and material omissions. Plaintiff was appointed as Lead Plaintiff by this Court on May 26, 2016 (Dkt. No. 40.) Plaintiff's trading in Amicus common stock is reflected in the certification filed on December 7, 2015 (Dkt. No. 23-2, Ex. B).

16. Defendant Amicus Therapeutics, Inc., is a Delaware corporation with its principal place of business in Cranbury, New Jersey. Amicus claims that it is a

"biotechnology company at the forefront of therapies for rare and orphan diseases," that "has a robust pipeline of advanced therapies for a broad range of human genetic diseases." Amicus common stock trades on the NASDAQ stock exchange under the ticker symbol "FOLD."

17. Defendant Crowley is the Chairman and Chief Executive Officer of Amicus, who is believed to reside in Princeton, New Jersey. Crowley also served on the Board of Directors of Scioderm until it was acquired by Amicus as described herein.

18. Defendant Barth, at all relevant times, has been Amicus' Chief Medical Officer, and is believed to own property in both Teaneck and Long Branch, New Jersey.

19. Defendants Crowley and Barth are described here in as the "Individual Defendants," and together with Amicus as the "Defendants".

20. The Individual Defendants, because of their position as top executive officers of Amicus, possessed the power and authority to control the content and form of Amicus' annual reports, quarterly reports, press releases, and presentations to the SEC, securities analysts, money and portfolio managers, and investors, *i.e.*, the market. Because of their positions with the Company and their access to material non-public information, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the

public, and that positive representations described herein were false and misleading.

Substantive Allegations

A. Amicus Therapeutics, Inc. is a small biotech company focused on commercializing migalastat.

21. Amicus is a biotechnology company that develops therapies for rare and orphan diseases. Amicus has developed a therapy—an oral small molecule pharmacological chaperone called migalastat—for the treatment of Fabry disease, which the Company hopes to market under the name Galafold.

22. Galafold is the Company's lead product candidate, and is a small molecule that can be used as a monotherapy and in combination with enzyme replacement therapy ("ERT") to treat Fabry disease. In the Annual Report on Form 10-K that the Company filed with the SEC on February 29, 2016, it stated that migalastat (*i.e.*, Galafold) was its "most advanced product candidate."

23. To study the safety and efficacy of oral Galafold, the Company has completed two Phase III studies of the drug: Study 011 and Study 012.

24. Study 011 (also called "FACETS") was a 24-month study of Fabry disease patients naïve to or not receiving ERT, which investigated the safety and efficacy of oral Galafold. The FACETS study was designed to measure the reduction of the disease substrate Globotriaosylceramide (or "GL-3") in the interstitial capillaries of the kidney following treatment with oral Galafold. The

study also measured clinical outcomes, including renal function, as secondary endpoints.

25. Study 012 (also called "ATTRACT") was a randomized, open-label 18-month study that investigated the safety and efficacy of oral Galafold, compared to standard-of-care infused ERTs.

26. Galafold is an important, bet-the-company drug for Amicus. For example, the Company informed investors in a presentation related to their August 5, 2015 earning conference call that the global market for Fabry treatments exceeded $1.1 billion in 2014 and would track toward $2 billion by 2021. And in a presentation attached to an 8-K the Company filed with the SEC on September 30, 2015, the Company further stated that its vision was to "treat all Fabry patients with an Amicus product if approved," and planned to sell migalastat (Galafold) for those treatments. Indeed, even the Company's stock ticker symbol, "FOLD", reveals how important Galafold is to Amicus' future.

27. As of September 2015, the Company had forecast having a "cash runway" that would run until 2017, and a vision to have Galafold "launched" in the United States by the end of 2016. The company's success in getting Galafold approved by the FDA was materially important to investors, and to Amicus' very existence as a company.

B. Amicus makes materially misleading statements about migalastat between March 19, 2015 and September 14, 2015.[1]

28. Between March 19 and September 14, 2015, Amicus repeatedly assured investors that the Company was on track to submit its new drug application ("NDA") to the FDA by the end of 2015, and that it would use a meeting scheduled with the FDA in the third quarter (what would eventually become the September 15, 2015 meeting) to discuss post-submission and post-approval activities. Through these statements, Amicus conditioned the market to believe that (a) everything was on track for Galafold; and (b) that the upcoming September FDA meeting would be centered completely around a discussion about post-NDA submissions and post-marketing activities for Galafold.

29. On March 19, 2015, Amicus issued a press release entitled *Amicus Therapeutics Provides Positive Global Regulatory Updates from EMA and FDA Meetings for Fabry Monotherapy,* and hosted a conference call with investors. The conference call was attended by Defendants Crowley and Barth, along with Bradley Campbell, Amicus' COO and Sara Pellegrino, Amicus' Associate Director of Investor Relations.

[1] Three initial complaints were filed in this District against Amicus. Two complaints named only Crowley as an individual defendant; one named both Crowley and Barth. That same complaint alleged a class period beginning on March 19, 2015 and ending on October 1, 2015; the other two began their class period on September 15, 2015. This consolidated amended class action complaint alleges misstatements during both periods: March 19, 2015 through September 14, 2015 and September 15, 2015 through October 1, 2015. Amicus' October 2, 2015 corrective disclosure revealed the truth of the misstatements and omissions made during both periods.

30. The March 19, 2015 press release began by informing investors that Amicus had "met very recently with regulatory authorities in Europe and the U.S. to discuss approval pathways for the oral small molecule pharmacological chaperone migalastat HCI ('migalastat') as a precision medicine monotherapy for Fabry patients who have amenable genetic mutations."

31. The March 19, 2015 press release explained that Amicus held a "Type C Meeting with the U.S. Food and Drug Administration (FDA)", stating:

> Amicus held a Type C meeting with the FDA earlier this week to review results from both Phase 3 Fabry clinical studies (Study 011 and Study 012) and to discuss the U.S. approval pathway for migalastat. Amicus and FDA officials discussed the migalastat monotherapy data, multiple potential approvable endpoints, and a path toward NDA submission under Subpart H. Dr. Barth also led the Amicus delegation for this meeting which also included one of the world's foremost Fabry nephrology experts. The key takeaways from the meeting include:
>
> - Amicus plans to submit an NDA for Accelerated Approval (Subpart H), which is only available to therapies for severe and life-threatening conditions that address significant unmet medical needs
>
> - For Accelerated Approval, FDA is open to considering several potential surrogate endpoints evaluated in the clinical studies of migalastat, including:
>
> - Substrate reduction (interstitial capillary GL-3)
>
> - Reduction in cardiac mass (left ventricular mass index, LVMi)

- Stabilization of kidney function (glomerular filtration rate)

- A post-approval (Phase 4) confirmatory study is required under Subpart H, and several potential protocol designs were discussed

- Amicus plans to schedule a pre-NDA meeting and to submit an NDA under Subpart H in the second half of 2015

32. Amicus' description of its meeting with the FDA was false or misleading because it failed to explain that its plans to submit its NDA in the second half of 2015 was not promised by the FDA, and was not certain or near certain.

33. During the teleconference that same day, Crowley stated as follows:

> We have also, as we get into these late-stage regulatory discussions and document preparations, *have also always been very conservative on our guidance* and we will continue to do that. *But when we have reason to be more optimistic, we will advance our timelines as necessary*.
>
> So let me just begin as background and state we tried in the release to give as much color as we could and as much of the tone and sentiment of the meetings, but they really were very, very positive and I just can't characterize them any way.

(Emphasis added.)

34. Crowley further described the Company's meetings with the FDA:

> Let me turn to the US FDA. That meeting was just two days ago [March 17, 2015] in Bethesda, and a number of senior people from FDA [were] there. Obviously, many

> people on the street and in the patient community [are] paying very close attention to this.
>
> . . .
>
> So certainly the FDA could have taken a very hard line and looked at the 011 study, which was initially intended for approval under Subpart H for accelerated approval, certainly could have looked at that and said that we had previously, years back, designated a six-month interim endpoint as the primary endpoint.
>
> There was no discussion around that. The discussion focused around the totality of the data, and the takeaways I think are pretty clear here. Again, I really want to compliment the FDA, the fact that senior leadership was there. They had taken clearly enormous amounts of effort to understand the data, were very well prepared, asked excellent questions, and clearly were working with us to find the path to approval.
>
> *And what we agreed to now will enable us to file the NDA in the second half of this year.*

(Emphasis added.)

35. Crowley continued:

> We are going to digest [the FDA's suggestions about a GI study] and in the pre-NDA meeting come with a proposal to the FDA. So it is great now that we have a path. We have been able to modify the timelines I think in a very, very positive way for patients and for shareholders. I can assure you that we are working tirelessly, as the release indicates, to make sure the MAA filing in the next quarter is of the highest quality and submitted in the most timely fashion possible.
>
> Likewise, we are now working on digesting the feedback from FDA and going into this pre-NDA meeting as soon

> as we can, with a filing anticipated in the second half of 2015. So I think a great day.

36. These statements were false and misleading because they failed to explain that the Company's plans to submit their NDA by the end of 2015 were not certain or near-certain, but were instead still speculative. The statement that "what we agreed to now will enable us to file the NDA in the second half of this year" was false because the Company had made no such agreement with the FDA.

37. Furthermore, these statements conditioned the market to think of the Company's next interaction with the FDA (which would eventually occur on September 15, 2015) as the final step before the NDA for Galafold could be submitted.

38. On May 5, 2015, the Company issued a press release reporting its financial results for the first quarter of 2015. The press release reiterated the Company's "positive meetings with regulatory authorities in Europe and the United States to discuss the approval pathway for migalastat for Fabry disease," and reinforced the Company's "plans to submit a new drug application (NDA) in the U.S. in the second half of [2015]."

39. These statements were false or materially misleading because the Company did not speak fully by admitting that its plan to submit an NDA by the end of 2015 was not certain or near-certain.

40. During a May 5, 2015 conference call, Defendant Crowley noted Amicus' "positive meetings with both European and United States regulators at the end of the first quarter," and stated that as a result of the Company's "face-to-face interaction based on the guidance from FDA from that [early 2015] meeting, we will be pursuing a Subpart H pathway for accelerated approval in the U.S." Crowley also stated that the Company continued to "be confident in the drug approval pathway in the U.S.," and was "actively preparing the new drug application, the NDA submission for the second half of [2015]," and that the "next interaction with the FDA will be a pre-NDA meeting in the middle of this year to finalize the details of the NDA."

41. These statements were false or materially misleading because the Crowley did not speak fully by admitting that the Company's plan to submit the NDA by the end of 2015 was not certain or near-certain. It was also false for Crowley to state that the purpose of the next interaction with the FDA would be to "finalize the details of the NDA," as the FDA had not made such a commitment, and in fact, the next meeting (held on September 15, 2015) caused Amicus to announce that it would not be able to submit its NDA in 2015.

42. On May 5, 2015, the Company filed a quarterly report for the period ended March 31, 2015 on a Form 10-Q with the SEC, which was signed by

Crowley (among others). The Form 10-Q stated the following regarding the NDA for Galafold:

> In the U.S., we plan to submit a new drug application ("NDA") for accelerated approval (Subpart H) with the U.S. Food and Drug Administration ("FDA") in the second half of 2015.

43. This statement was false or materially misleading because the Company did not speak fully by admitting that its plan to submit an NDA by the end of 2015 was not certain or near-certain.

44. On June 11, 2015 the Company filed a registration statement on a Form S-3 with the SEC, which incorporated by reference the information contained in a shelf registration statement on Form S-3 filed with the SEC on March 3, 2015, and declared effective on May 4, 2015. On June 12, 2015, the Company filed a prospectus supplement and an accompanying prospectus on a Form 424B5 with the SEC, which forms part of the registration statement (collectively, the "Registration Statement"). The Registration Statement was signed by Crowley, among others.

45. The Registration Statement stated the following regarding the Company's NDA for Galafold:

> We plan to submit a new drug application ("NDA") to the FDA in the second half of 2015. We have reported Phase 3 data in both treatment naïve patients ("Study 011" or "FACETS") and ERT switch patients ("Study 012" or "ATTRACT"). Positive results from these

> studies have shown that treatment with Galafold has resulted in reductions in disease substrate, stability of kidney function, reductions in cardiac mass, and improvement in gastrointestinal symptoms in patients with amenable mutations confirmed by a validated assay.

46. This statement was false or materially misleading because the Company did not speak fully by admitting that its plans to submit an NDA by the end of 2015 were not certain or near-certain.

47. On June 17, 2015, the Company issued a press release announcing the closing of the public offering. The Company issued approximately 19.5 million shares at $13.25 per share. Amicus grossed approximately $258.8 million through the offering.

48. On August 5, 2015, the Company issued a press release reporting its financial results for the second quarter ended June 30, 2015. In the press release, Crowley stated that Amicus planned "to submit our U.S. marketing application [for Galafold] in the second half of this year."

49. The press release also promoted the Company's upcoming meeting with the FDA:

> In the U.S., a pre-New Drug Application (pre-NDA) meeting is scheduled for the third quarter with the Food and Drug Administration (FDA) to discuss the content of the planned NDA (Subpart H) and proposed Phase 4 post-marketing commitments for Galafold in the second half of this year.

50. These statements were false or materially misleading because the Company and Crowley did not speak fully by admitting that the Company's plans to submit an NDA by the end of 2015 were not certain or near-certain. The Company and Crowley also failed to accurately represent the purpose of the meeting with the FDA planned for September; the press release states that the meeting was scheduled to "discuss the content of the planned NDA (Subpart H) and proposed Phase 4 post-marketing commitments for Galafold," but in fact the FDA had no such agenda.

51. During an August 5, 2015 conference call to discuss the Company's second quarter results, Defendant Barth was asked about the Company's pre-NDA meeting scheduled for September and whether the Company expected "the focus of that meeting to differ if at all from previous interactions you've had with the FDA like the Type-C meeting." Barth responded:

> Yes. The pre-NDA meeting, it's really going to be based on requests that we got at the Type-C meeting and the discussion. So it's a follow-on with regard to the content of the NDA, the under sub part H. *And specifically it's going to be forward focused on the proposed design for the Phase IV commitments, confirmatory studies that are necessary part of sub-part H.*
>
> So, we're picking up where we left off at the Type-C meeting and providing more details to the FDA with regard to our plan which and they have requested a GI study, what that study will look like as well as additional supportive data that we'd be able to provide out of the registry.

> And we are quite far along in the NDA, I can't give a specific percentage but from the moment that the MAA [Marketing Authorization Application] went in, we turned around and started converting that as it were to an NDA. *So we're very much on track for submission this year and following the pre-NDA meeting.*

(Emphasis added.)

52. These statements by Barth were false and misleading because Barth failed to disclose that the Company's purported plans to submit an NDA by year end were speculative, and were not certain or near-certain. Furthermore, Barth's statements did not accurately describe the purpose of the Company's forthcoming September FDA meeting, as that meeting was not "forward focused on the proposed design for the Phase IV commitments, confirmatory studies that are necessary part of sub-part H." Those statements falsely assume that the FDA had already agreed about the successful outcome of the forthcoming meeting.

53. On August 5, 2015, the Company filed a quarterly report for the period ended June 30, 2015 on a Form 10-Q with the SEC, which was signed by Crowley (among others). The Form 10-Q stated:

> In the United States, the Company plans to conduct a pre-new drug application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA") and to submit an NDA for Galafold under Subpart H (accelerated approval) in the second half of 2015 for accelerated approval.

54. This statement was false and misleading because it failed to disclose that the Company's purported plans were speculative, and were not certain or near-certain. Similarly, the statement does not accurately describe the purpose of the Company's then upcoming meeting with the FDA. The statement implies that the FDA has agreed that the meeting will be focused on activities post-NDA submission and approval, but the FDA had given Amicus no such assurances.

55. The market accepted Amicus statements as fact. On August 6, 2015, an analyst at Janney Montgomery Scott wrote that Amicus "expects to discuss the planned Subpart H NDA and proposed Phase IV post-marketing program with the [FDA] and anticipates submitting an NDA for Galafold during [the second half of 2015]."

C. During a critical two-week period, Amicus repeatedly misrepresents its September 15, 2015 meeting with the FDA.

Defendants meet with the FDA on September 15, 2016

56. On September 15, 2016, shortly after meeting with the FDA, the Company issued a press release, which stated as follows:

> Amicus Therapeutics (Nasdaq:FOLD), a biotechnology company at the forefront of therapies for rare and orphan diseases, today announced that a Pre-NDA meeting was held with the U.S. Food and Drug Administration (FDA) to discuss the oral small molecule pharmacological chaperone migalastat for the treatment of Fabry disease. The unique mechanism of action of migalastat represents a new personalized medicine option for Fabry patients who have amenable mutations.

> Based on FDA feedback at the Pre-NDA meeting, reduction in disease substrate (kidney interstitial capillary GL-3) will serve as the primary endpoint, *supported by the totality of data from completed clinical studies. Amicus remains on track to submit an NDA in the fourth quarter of 2015 under Accelerated Approval*, which is only available to therapies for severe and life-threatening conditions that address significant unmet medical needs.[1] Discussions with the FDA on the Phase 4 program required for a Subpart H approval have focused on a study of the effect of migalastat on gastrointestinal symptoms associated with Fabry disease. In addition to the NDA submission, Amicus intends to submit for review the protocol for the Phase 4 study confirming the positive effects of migalastat on gastrointestinal symptoms in these patients.
>
> "Our collaborative Pre-NDA meeting represents a significant milestone for the Fabry community in the United States and is a great example of FDA and industry working together to advance innovative therapies for people living with debilitating genetic disorders," stated John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics. "The guidance provided by FDA during the Pre-NDA meeting further reinforces our confidence in the NDA package and post-marketing confirmatory study we are preparing for submission by the end of this year. In addition, our marketing submission for migalastat in Europe is already being reviewed under Accelerated Assessment and an Opinion is expected by year-end. With defined regulatory pathways for migalastat in both the U.S. and EU, we are rapidly executing our global strategy to bring this novel personalized medicine to as many people living with Fabry disease as quickly as possible."

(Emphasis added.)

57. Given the Company's statements made between March and September of 2015 and described above, this press release represented to the market that the FDA had provided a positive indication, at this September 15 meeting, that Amicus could submit its NDA, under Accelerated Approval status, by the end of 2015. Indeed, the Company specifically stated that Amicus "remains on track to submit an NDA in the fourth quarter of 2015 under Accelerated Approval." Crowley's statement that the "guidance provided by FDA during the Pre-NDA meeting further reinforces our confidence in the NDA package and post-marketing confirmatory study we are preparing for submission by the end of the year," and claim that Amicus had a "defined regulatory pathway[] for migalastat in . . . the U.S.," told investors that Amicus' NDA was on track as previously promised by the Company.

Amicus and Crowley tell investors that the Company is "on track" to submit its NDA in 2015 at a major investment conference

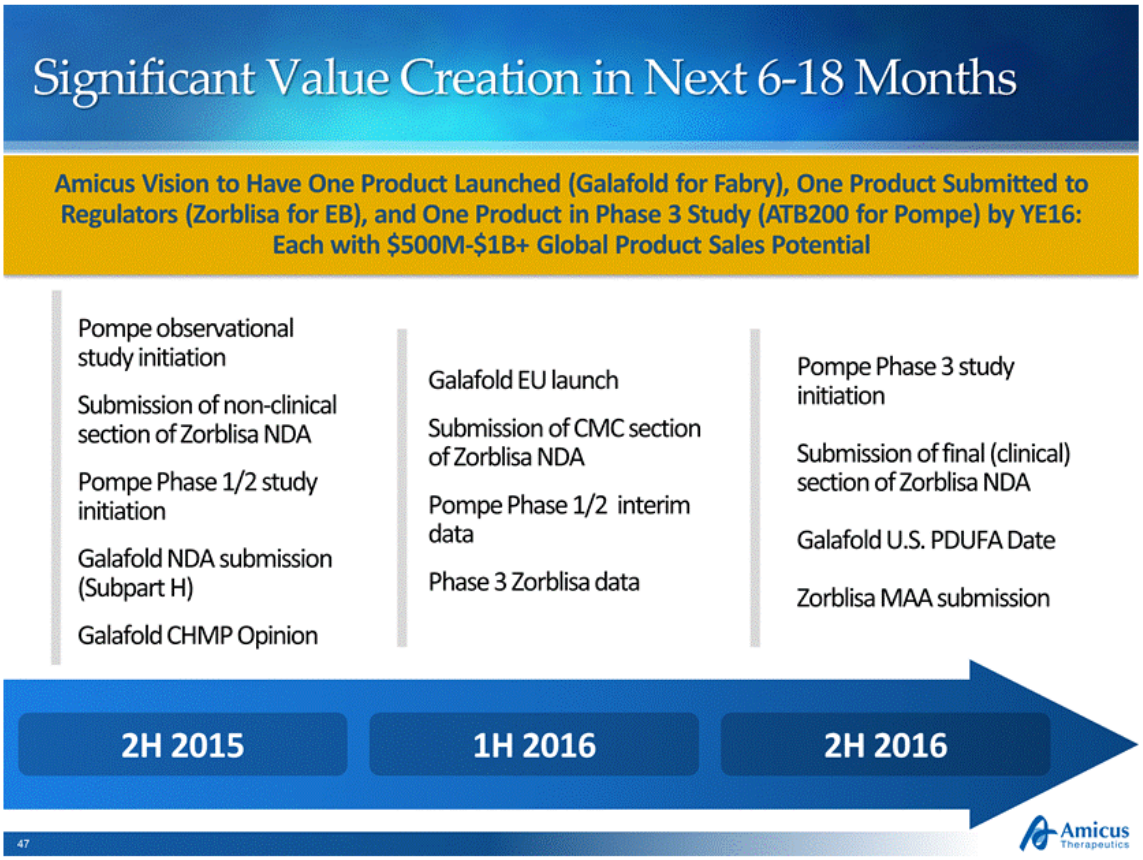
58. Crowley participated in a "fireside chat" at an event hosted by Leerink Partners called the "Rare Disease Roundtable" at 2:45 pm Eastern Time on September 30, 2015. During the chat, Crowley stated:

> We continue to have discussions most recently at a pre-NDA meeting and while GL-3 is an accepted surrogates in Fabry disease and one that *we may pursue and we issued the press release of course a couple of weeks ago saying that we are on track for NDA activities with Fabry disease*, we are continuing our discussions with the FDA to look at strengthening that application with other

> potential surrogate endpoints and potentially other clinical data that we may provide to the agency.
>
> So that is an ongoing discussion. It is not yet by any means a slam dunk in the United States. *We have more work to do including finalizing our Phase 4 plan with the US FDA but so far from a timing standpoint, everything remains on track. . .*

(Emphasis added.)

59. A September 30, 2015 presentation published by Amicus as an exhibit on Form 8-K entitled "Corporate Overview" also stated that Amicus was on track for "significant value creation in next 6-18 months," and stated that Amicus planned its "Galafold NDA submission (Subpart H)" in "2H 2015":



Amicus reveals the truth about its September 15 FDA meeting

60. The truth about the outcome of Amicus' September 15 FDA meeting was revealed to the market early on Friday morning, October 2, 2015, when Amicus issued a corrective press release innocuously entitled "Amicus Therapeutics Provides U.S. Regulatory Update for Migalastat Monotherapy."

61. The press release stated:

> CRANBURY, N.J., Oct. 2, 2015 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq:FOLD), a biotechnology company at the forefront of therapies for rare and orphan diseases, today announced additional regulatory guidance from the U.S. Food and Drug Administration (FDA) on the oral small molecule pharmacological chaperone migalastat for the treatment of Fabry disease.
>
> Amicus has received **final FDA minutes from the September pre-NDA meeting and has conducted additional follow-up interactions with the Agency *this week***. In conjunction with the Agency, Amicus is further evaluating several U.S. pathways including ***potentially*** generating additional data on migalastat's effect on gastrointestinal symptoms in Fabry disease to support submission requesting full approval as well as a Subpart H strategy. In addition, the Agency has requested ***further integration of existing clinical data across studies*** which will require more time to complete. Based on this guidance from the FDA, Amicus does not anticipate being in a position to submit the NDA for migalastat monotherapy in the United States by the end of this year. The timing of an NDA submission will be based on the determination of the optimal regulatory pathway.
>
> "Amicus remains committed to making migalastat available to Fabry patients with amenable mutations in

> the U.S. as rapidly as possible. We are appreciative of the FDA's ongoing collaboration in this program," stated John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics.

(Emphasis added.)

62. Amicus also hosted a conference call for investors and analysts on October 2, 2015. During the call, Crowley stated:

> So now let me get specifically to the delay in the NDA filing. There are two reasons for this. Number one, ***and we confirmed this yesterday with FDA***, the FDA has asked for the integration of the data, safety, and efficacy together with additional analyses of that data for both of our Phase III studies, Study 011 and Study 012. ***We had been planning on providing the FDA with Study 011 as the sole basis of approval supplemented by 012. The FDA asked for both studies to be fully integrated.*** That has caused a specific delay as we've analyzed that very carefully. The view of our clinical and regulatory teams is that will take several more months to complete, so that we would not be in a position to file any NDA by the end of this year. That was part of the guidance that we updated in the release this morning.
>
> Secondly, we continue to engage in a constructive dialogue with FDA around the appropriate potential basis for approval of migalastat monotherapy in the United States. As you know, based on the meeting that we just recently held in person with FDA, ***we had guided that we would be filing under Subpart H for conditional approval based on the interstitial capillaries in the GL3. What we're guiding to now is that we are still working with FDA on Subpart H, but beyond [I.C. GL3], and we intend to continue to dialogue with FDA around what we believe are other potential Subpart H approvable endpoints together with our Phase IV commitment***. That's not yet resolved with FDA of what those potential

> multiple pathways may be under Subpart H, so we will have to continue that dialogue with FDA as we do the work internally to integrate those databases in this study.

(Emphasis added.)

63. The October 2 statement that "Amicus does not anticipate being in a position to submit the NDA for migalastat monotherapy in the United States by the end of this year" because of "final FDA minutes from the September [15] pre-NDA meeting," and "additional follow-up interactions with the [FDA]" contradicted the statements made by Amicus and Crowley on September 15, 2015, after the meeting with the FDA was complete.

64. Crowley's statement on September 30, 2015 at the Leerink Partners Rare Disease Roundtable that "so far from a timing standpoint, everything remains on track" regarding the NDA submission was false and misleading, as Amicus admitted that it was in discussions with the FDA during the week of September 28, 2015 regarding the data it would need to submit to support its NDA filing and just 42 hours later, Amicus and Crowley both acknowledged more data would have to be submitted to the FDA to support an NDA filing.

65. The October 2 statement also contradicted the statement made in the Corporate Overview presentation from September 30, 2015 which stated that "Galafold NDA submission (Subpart H)" was scheduled for "2H 2015."

66. The "final minutes" from the FDA meeting, and the result of the FDA's analysis (*i.e.*, that Amicus would need to integrate data from its two studies and focus on a different endpoint, which would take a significant amount of time) simply would not have come as a surprise to Crowley or Amicus. The FDA issues guidance to companies such as Amicus about how it expects meetings at the FDA to proceed. In *Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants*, the FDA advises:

> Before the end of the meeting, FDA attendees and the requested attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the requester will be asked to present the summary to ensure that there is mutual understanding of meeting outcomes and actions. FDA staff can add or further clarify any important points not covered in the summary and those items can be added to the meeting minutes.

67. Amicus and Crowley either followed clear FDA guidance and left the September 15 meeting with a full understanding of "discussion points, agreements, clarifications, and action items," and then deliberately issued false statements about the meeting to the press and investors on September 15 and 30, or they acted recklessly and were willfully blind to the FDA's cautions and admonitions during the meeting.

68. Furthermore, it is simply not conceivable that, at the time Crowley appeared at the September 30 Leerink Partners event and stated that "everything

remains on track," he did not already know that the Company could no longer submit its NDA by the end of 2015. Amicus' October 2 press release states that the Company had "additional follow-up interactions with the [FDA] this week" (*i.e.*, the week of September 28 to October 2, 2015). Those multiple "interactions" could not have all occurred on Thursday, October 1; at least some interactions must have occurred before Crowley made material misstatements in the late afternoon at the Wednesday, September 30 Leerink Partners event.

69. Many of the experienced financial analysts who cover Amicus attended the October 2, 2015 teleconference, and were shocked by the news. Ritu Baral of Cowen and Company asked "[W]hy do you feel that it took the meeting minutes to understand where the FDA was coming from?" while Joseph Schwartz of Leerink Partners asked "How do you explain to us specifically what you heard in the pre-NDA meetings that is at odds with what the FDA minutes contain? Just because I'm a little bit confused about how the interpretation is so different." Crowley responded by telling Baral that Amicus "took a different interpretation of whether [the FDA] would be open to that full approval," and told Leerink that Amicus' "very strong interpretation" of the meeting was that "the only pathway available to us would be a Subpart H approval pathway based on ICGL-3," but admitted that the FDA did not ultimately agree and would require "further discussion" with Amicus.

70. Leerink Partners analyst Joseph Schwartz further stated that the October 2 press release came as a "huge surprise" to investors. (Schwartz himself hosted the Leerink Partners fireside chat on September 30, described above.) It is no wonder that Schwartz, Leerink, and the market as a whole were shocked: Crowley told them the exact opposite less than 48 hours earlier at the Leerink fireside chat.

D. Statements made by Amicus and Crowley on September 15, 2015 and September 30, 2015 were false and misleading and omitted to disclose material facts.

71. The statement from the September 15, 2015 press release "[b]ased on FDA feedback at the Pre-NDA meeting, reduction in disease substrate (kidney interstitial capillary GL-3) will serve as the primary endpoint, supported by the totality of data from completed clinical studies" was false because Crowley admitted on October 2, 2015 during the analyst conference call that Amicus was "still working with FDA on Subpart H, but beyond [interstitial capillary] GL-3, and [Amicus] intend[s] to continue to dialogue with FDA around what we believe are other potential Subpart H approvable endpoints." Furthermore, Crowley's October 2 statement that Amicus had previously been "planning on providing the FDA with Study 011 as the ***sole basis of approval supplemented by 012***" is contradicted by the Company's September 15 press release, which stated that the NDA would be "supported by the ***totality of data from completed clinical studies***".

Furthermore, Crowley's use of the word "confirmed" (rather than, for example, "learned") during the October 2 teleconference ("[W]e confirmed this yesterday with the FDA, the FDA has asked for the integration of the data, safety and efficacy together with additional analyses of that data…") reveals that the company did not learn for the first time on October 1 about the FDA's concerns or that those concerns would cause the delay of the NDA. Moreover, in its press release, Amicus admitted that had "received final FDA minutes from the September pre-NDA meeting and has conducted additional follow-up interactions with the Agency *this week*," strongly suggesting that Amicus was in receipt of the final minutes during the week of September 28, 2015 and had "additional follow-up interactions" with the FDA that week regarding its submission of an NDA for migalastat. In fact, Crowley's statement is highly suspect because he admitted that Amicus "analyzed that very carefully," strongly suggesting that Amicus spent more than a day analyzing what the FDA was asking for.

72. The statement from the September 15, 2015 press release that "Amicus remains on track to submit an NDA in the fourth quarter of 2015 under Accelerated Approval" was false because Amicus knew or was reckless in not knowing that the result of the FDA meeting was such that Amicus would not be able to submit its NDA by the end of 2015 because the agency was going to require the Company to integrate data from two studies and to shift its focus on

interstitial capillaries in the GL-3, as reflected in the Company's October 2 announcement and Crowley's statements on the October 2 conference call.

73. Crowley's statement from the September 15, 2015 press release "[t]he guidance provided by FDA during the Pre-NDA meeting further reinforces our confidence in the NDA package and post-marketing confirmatory study we are preparing for submission by the end of this year," and the Company's statement in the September 30, 2015 presentation that Amicus was on track for "significant value creation in next 6-18 months," and planned its "Galafold NDA submission (Subpart H)" in "2H 2015" were all false because Crowley and Amicus knew at the time those statements were made that the FDA was going to ask Amicus to fully integrate its data from Study 011 and Study 012, and that this would cause the Company to delay the issuance of its NDA. This is evidenced by, among other things, the statements made by Crowley during the October 2, 2015 teleconference and the Company's October 2, 2015 press release described above.

74. Crowley's statement on September 30, 2015 at the Leerink fireside chat that "We have more work to do including finalizing our Phase 4 [*i.e.*, post-approval] plan with the US FDA but so far from a timing standpoint, everything remains on track . . ." was materially false and misleading because by September 30, 2015, the Company was aware that the FDA was going to require Amicus to fully integrate its data from Study 011 and Study 012, and that this would cause the

Company to delay the issuance of its NDA, as evidenced by, among other things, the statements made by Crowley during the October 2, 2015 teleconference and the Company's October 2, 2015 press release described above.

75. Amicus omitted to disclose the material facts that the FDA was asking Amicus to fully integrate its data from Study 011 and 012, which would cause a significant delay as integrating the data would push filing for the NDA well beyond year-end 2015 and that the FDA did not agree that Subpart H approval could be supported by a study of the effect of migalastat on gastrointestinal symptoms. Amicus also failed to disclose that it was taking a "different" and "very strong" interpretation of the feedback it received from the FDA at the September 15, 2016 meeting. By omitting to disclose that Amicus and Crowley were taking a "different" and "very strong" interpretation of what the FDA conveyed at the meeting, they misled investors by omitting disclose that they were being overly optimistic in their interpretation of the information the FDA would require to support an NDA. In addition, Defendants omitted to disclose that the only pathway to Subpart H approval was based on ICGL-3 but that the FDA did not agree with or approve this at the September 15, 2016 meeting, which Defendants omitted to disclose. The disclosure of these facts were necessary to make the statement made in the September 15, 2015 press release not misleading.

E. Events between September 15, 2015 and October 2, 2015 show Defendants' culpability for making the false statements.

76. The period between September 15, 2015, when the Company met with the FDA and issued its positive press release about the meeting, and October 2, 2015, when it admitted that its September 15, 2015 press release was false, was a busy time at Amicus. Insiders sold over $1 million in their stock, and the Company completed an acquisition of Scioderm, a small private biotech startup of which Crowley was a Board member. While the market was unaware of the September 15 misstatements, events at Amicus show that insiders, including Crowley, knew exactly what was coming.

Amicus completes its acquisition of Scioderm after changing the terms of the acquisition to pay more cash and less Amicus stock than previously agreed

77. On August 31, 2015, Amicus had announced by press release that it intended to acquire Scioderm.

78. Crowley, in addition to serving as Amicus' Chairman and Chief Executive Officer, also served on the Board of Directors of Scioderm.

79. When the transaction was initially announced on August 30, 2015, Amicus had agreed to pay Scioderm shareholders "$229 million, of which $125 million will be paid in cash and $104 million will be paid through the issuance of 7 million newly issued Amicus shares."

80. The transaction with Scioderm closed on September 30, 2015: after the Company's false September 15, 2015 press release but before the Company made its corrective disclosure on October 2, 2015. In other words, shares of Amicus were still trading at inflated levels.

81. When the closing of the transaction was announced on September 30, 2015, Amicus also announced that terms of the transaction had changed, as a result of a September 30, 2015 amendment to the merger agreement with Scioderm. Now, $141 million would be paid in cash and only $88 million would be paid in Amicus shares.

82. Crowley, who served as both a member of Scioderm's board and the Chief Executive and Chairman of Amicus, oversaw a modification of the original agreement between Amicus and Scioderm that provided Scioderm shareholders (including Crowley himself) with more cash and less Amicus stock. Of course, the value of Amicus stock would drop in value only two days later.

83. Amicus' Chief Financial Officer William D. Baird, III ("Baird") signed the Amendment to Agreement and Plan of Merger reflecting this change in consideration on September 30, 2015.

Amicus insiders sell shares of Amicus following the Company's September 15 press release

84. Between September 15 and October 2, numerous Amicus insiders (including the members of senior management likely to have attended the critical

FDA meeting) sold their shares of Amicus on the public market. The value of the shares would be cut by more than half only a few weeks later.

85. Hung Do, Ph.D., Amicus' Chief Scientific Officer, sold 25,000 shares on September 15, 2015 at an average price of $17.7467 per share, grossing approximately $443,667.

86. Bradley Campbell, Amicus' President and Chief Operating Officer, sold 13,001 shares on September 21, 2015 at an average price of $16.7838 per share, grossing approximately $218,206.

87. Baird sold 15,236 shares on September 21, 2015 at an average price of $16.7783 per share, grossing approximately $255,634.

88. Kenneth W. Peist, Amicus Vice President, Legal and Intellectual Property, sold 10,000 shares on October 1, 2015 at an average price of $13.1362 per share, grossing approximately $131,362.

89. Daphne Quimi, Amicus' Vice President, Finance and Corporate Controller, sold 11,250 shares on October 1, 2015 at an average price of $13.1343 per share, grossing approximately $147,760.

90. These insider sales grossed approximately $1.2 million. Had these insiders waited until the truth was revealed on October 2 to sell their shares at $6.39 per share (the closing price of Amicus shares on October 2), they would

have instead grossed only approximately $480,000. Selling during the window was worth over $720,000 to these insiders (and at the expense of the Class).

Class Action Allegations

91. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a Class of all persons and entities who purchased or otherwise acquired Amicus common stock between March 19, 2016 and October 1, 2015, inclusive. Excluded from the Class are Defendants, directors, and officers of Amicus, as well as their families and affiliates.

92. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

93. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include (a) whether the Exchange Act was violated by Defendants; (b) whether Defendants omitted and/or misrepresented material facts; (c) whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; (d) whether Defendants knew or recklessly disregarded that their statements were false and misleading; (e) whether the price of Amicus stock was

artificially inflated; and (f) the extent of damages sustained by Class members and the appropriate measure of damages.

94. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

95. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

96. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

Fraud on the Market

97. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things: (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period; (b) The omissions and misrepresentations were material; (c) the Company's common stock traded in efficient markets; (d) the misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and (e) Plaintiff and other members of the Class purchased Amicus common stock between the time Defendants misrepresented or

failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

98. At all relevant times, the market for Amicus common stock was efficient for the following reasons, among others: (a) Amicus filed periodic public reports with the SEC; and (b) Amicus regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysists, and other similar reporting services. Plaintiff and the Class relied on the price of Amicus common stock, which reflected all information in the market, including the misstatements by Defendants.

No Safe Harbor

99. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

100. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

Loss Causation

101. On October 2, 2015, before the markets opened, Amicus disclosed that it "does not anticipate being in a position to submit the NDA for migalastat monotherapy in the United Stated by the end of this year," contrary to its prior public statements. When the market closed on October 1, 2015, before the corrective disclosure was made, Amicus shares traded at $13.75 per share. The October 2, 2015 corrective press release was issued before the stock market opened; when trading began in Amicus stock that morning, shares opened at $5.98 per share and closed at $6.39 per share at the end of trading on October 2, 2015. This was a drop of over 53.5%. The drop was directly attributable to the false statements alleged herein and the corrective disclosure made on the morning of October 2, 2015.

Causes of Action

Count I
Violation of § 10(b) of the Exchange Act and
Rule 10b-5 Promulgated Thereunder
(Against All Defendants)

102. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

103. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material

facts necessary to make the statements, in light of the circumstances under which they were made, not misleading.

104. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted of state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of conduct which operated as a fraud and deceit upon those who purchased or otherwise acquired Amicus securities during the Class Period.

105. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Amicus common stock. Plaintiff and the Class would not have purchased Amicus stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count II
Violation of § 20(a) of the Exchange Act
(Against the Individual Defendants)

106. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

107. Crowley and Barth acted as controlling persons of Amicus within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-

level positions at the Company, Crowley and Barth had the power and authority to cause or prevent Amicus from engaging in the wrongful conduct described above.

108. Crowley and Barth were provided with or had unlimited access to the press releases and statements alleged by Plaintiff to be misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of these materials or to cause them to be corrected so as not to be misleading.

Prayer for Relief

Wherefore, Plaintiff prays for relief and judgment as follows:

A. Determining that this action is a proper class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory and punitive damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;

C. Awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

D. Awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

Jury Trial Demand

Plaintiff demands a trial by jury.

July 11, 2016

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